

## **REMARKS**

Claims 5, 6, 8, 9, 11, 12, 14-23, 25-27 and 29 are pending. Claims 9, 11, 12, 14-23, and 25 have been deleted. Claims 5, 6, 8, 26, 27, and 29 have been amended.

### **Rejection under 35 U.S.C. § 112, First paragraph**

(1) Claims 5, 6, 8, 9, 11, 12, 14-23, 25-27 and 29 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description.

Applicants have amended the claims to limit the subject matter to methods to treat sexual dysfunction using dopamine agonists that are more selective for D4 receptors than for D2 receptors, specifically using two compounds that were widely described in the specification.

(2) Claims 5, 6, 8, 9, 11, 12, 14-23, 25-27 and 29 are rejected under 35 U.S.C. § 112, first paragraph, because the specification is not enabled for the compounds that are dopamine D4 agonists, with the exception of the two particular compounds listed in claims 11 and 12. Applicants have deleted claims with broad scope, leaving the scope of the claims limited to those compounds that are dopamine receptor agonists with a higher selectivity for D4 receptors over D2 receptors as described in the specification.

In view of the deletion and the foregoing remarks, Applicants respectfully request the Examiner to reconsider the claims and respectfully request withdrawal of the rejection of claims 5, 6, 8, 9, 11, 12, 14-23, 25-27 and 29 under 35 U.S.C. § 112, first paragraph.

### **Rejection under 35 U.S.C. § 103(a)**

Claims 1, 2, 4-6, 8, 9, 11, 12, 14-23, 25-27 and 29 are rejected under 35 U.S.C. § 103(a), as being unpatentable over Fliri *et al.* WO 99/09025 (hereinafter “WO 99/09025”) and Glase *et al.* (IDS, hereinafter “Glase”) in view of Fliri *et al.* US Patent No. 5,883,094 (hereinafter ‘094), and Faraci *et al.*, US Patent No. 5,889,010 (hereinafter ‘010), and in further view of El-Rashidy *et al.*, US Patent No. 5,779,606 (hereinafter ‘606).

Applicants have restricted the scope of the claims to methods of treating sexual dysfunction using two specific compounds, namely N-{[4-(2-cyanophenyl)-1-piperazinyl]methyl}-3-methylbenzamide and 5-fluoro-2-{[4-(2-pyridinyl)-1-

piperazinyl)methyl}-1H-indole. In view of this amendment the references of Fliri *et al.* US Patent No. 5,883,094 and Faraci *et al.*, US Patent No. 5,889,010 do not apply as prior art references and should be removed from consideration.

As recognized by the Examiner, WO 99/09025 and Glase do not teach expressly the employment of dopamine D4 agonists for treating sexual dysfunction. These references teach the usefulness of the dopamine D4 agonists to treat CNS disorders. El-Rashidy *et al.*, US Patent No. 5,779,606 teaches the use of apomorphine to treat sexual dysfunction. Apomorphine is a non-selective dopamine agonist, which causes side effects, especially emesis. Applicants have described the effects of the two compounds of the present application, namely N-{[4-(2-cyanophenyl)-1-piperazinyl)methyl}-3-methylbenzamide and 5-fluoro-2-{[4-(2-pyridinyl)-1-piperazinyl)methyl}-1H-indole, which are dopamine receptor agonists specific for D4 receptors over D2 receptors. These results indicate a specific improvement in the sexual behavior on mammals without the liability of the emetic effect.

In view of the deletion and the foregoing remarks, Applicants respectfully request the Examiner to reconsider the claims and respectfully request withdrawal of the rejection of claims 5, 6, 8, 9, 11, 12, 14-23, 25-27 and 29 under 35 U.S.C. § 103(a).

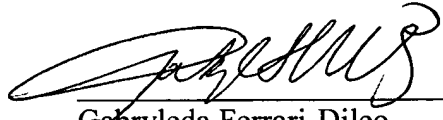
## **CONCLUSION**

In view of the new set of claims and the aforementioned remarks, Applicants respectfully believe that the application is now in condition for allowance and respectfully request that the Examiner to reconsider the application and withdraw all outstanding rejections.

Should the Examiner have any concerns regarding the above, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,  
Jorge D. Brioni, et al.

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